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ONE HUNDRED SEVENTH CONGRESS

# Congress of the United States

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February 15, 2002

## URGENT – FOR PHYSICIAN’S PERSONAL ATTENTION

Subject: Suicide Prevention – Fully Informed Consent With Accutane

Dear Doctor:

On December 5, 2000, the Committee on Government Reform, which I chair, conducted a hearing regarding the potential link between the acne drug Accutane and depression and suicide. Accutane (isotretinoin) is a drug approved by the FDA to treat the most serious form of acne — a type that is painful, permanently disfiguring, and does not respond to other acne treatments. However, the FDA has recognized that this medication has a serious and potentially dangerous side effect. In some instances, Accutane users become severely depressed and vulnerable to thoughts of suicide.

To date, the Food and Drug Administration (FDA), through its MedWatch reporting system, has received reports of 140 suicides, 176 suicide attempts, and 1,156 serious depression-related events related to Accutane. Many of these reports were for adversely affected teenagers. Given that MedWatch is a voluntary reporting system and that FDA officials in the past have suggested that only between one and ten percent of adverse events are reported, the actual numbers may be much higher.

In February 1998, the FDA issued warnings to physicians and advised the manufacturer, Roche Pharmaceuticals to include the following warning in the labeling:

*“Psychiatric Disorders: Accutane may cause depression, psychosis and, rarely, suicidal ideation, suicide attempts and suicide. Discontinuation of Accutane therapy may be insufficient; further evaluations may be necessary...of patients reporting depression, some reported that the depression subsided with discontinuation of therapy and recurred with reinstitution of therapy.”*

At our Committee hearing, we heard testimony from a number of families whose children had either committed suicide or made an attempt while using Accutane. In their testimony, these families raised two serious concerns. The purpose of this letter is to share these concerns with you in hopes that it will help you better address these issues with your patients.

**1. While Accutane is meant as a treatment of last resort, it is sometimes prescribed before trying alternatives with less serious side effects:**

The FDA approved Accutane for use for severe nodular cystic acne. The FDA-approved labeling specifically highlights that this product is not to be considered as a product of first choice:

*“Because of significant adverse effects associated with its use, Accutane should be reserved for patients with severe nodular acne who are unresponsive to conventional therapy, including systemic antibiotics.”*

However, we learned from witnesses that Accutane is sometimes being used for less severe forms of acne and before other treatments have been tried.

Michael Bauman, who lost his son Dan to suicide while on Accutane, testified about running into a friend who was picking up a prescription for Accutane:

*“When I asked her if she was aware of the potential side effects, she looked at me like I was nuts. When I asked if she was counseled by her son’s dermatologist; she said she was not. I asked if this drug was prescribed when other drugs had failed and found out that it had been prescribed first before any other remedies had been tried. I then asked to look at the labeling and letter that came with her prescription and found that it made no mention of depression or suicide and the pharmacist said nothing about these potential dangers.”*

Mr. Charles Stone, whose son Clay died in January 2000, stated:

*“In October 1999, at the age of 16, his treating physician decided to put Clay on Accutane for his mild acne.”*

**2. Patients and their parents are not always advised by their physicians of the serious side effects associated with Accutane:**

Tragically, we learned that families had not been fully informed about the suicide risks associated with Accutane. The FDA’s warning to physicians was sent in February 1998. As we learned during our hearing, patients who were prescribed Accutane after this were not

always informed of this new warning by their physician. Daniel Bauman began taking Accutane in June 1999 and received two brochures to review prior to beginning therapy. Neither brochure mentioned depression or suicide. Daniel committed suicide in December 1999. His mother, Mrs. Bauman, testified:

*“I got on line and used the two key words: Accutane and suicide and found the FDA’s MedWatch News dated February 26, 1998: ‘important new safety information about Accutane.’ In addition, I also discovered that the brochures Daniel’s dermatologist gave us were copywritten in 1996 and 1997, respectively. The brochures had no adverse reactions reporting depression, psychosis, suicidal ideations, suicide attempts and suicide. I was finding it very hard to believe that Daniel’s dermatologist had no idea or updated information to hand out to his patients.”*

Mr. Stone also testified that they were not informed about the potential link to suicide:

*“There was never any mention of suicide as a side effect. The information that Clay brought home from the dermatologist was a brochure dated 1994 and made no mention of suicide.”*

As has been widely reported, the teenage son of Michigan Congressman Bart Stupak committed suicide while taking Accutane. In a statement released October 5, 2000, Congressman Stupak said:

*“As a parent, I would have wanted to know of the risk of depression, suicide ideation and suicide, before allowing my child to take this drug.† As a legislator, I believe that the public has a right to know of all risks associated with prescription drugs.”*

Our hearing contributed to the development and implementation of a comprehensive program to ensure that Accutane patients, and the parents of minors prescribed Accutane, are fully informed of this concern and can make informed decisions regarding Accutane treatment. This program includes important precautionary information, including an explicit informed consent form and a patient-friendly Medication Guide.

This is why I am contacting you and asking for your assistance. If you are prescribing Accutane to your patients, or referring patients to a dermatologist for this acne drug, please discuss all the potential risks, monitor the patient’s emotional status during and after the use of Accutane, and otherwise comply with the elements of the above-referenced program. I am sure you agree that if this added effort saves just one life, the time will have been well spent.

While the focus of our hearing and of this letter concerns the need for fully informed consent regarding the potential risk of depression or suicide, the risk of birth defects and fetal deaths are also of concern. I would also urge that you closely review the newly published “Guide to Best Practices,” and that you work closely with your patients to ensure that no unborn child is put at risk.

If you would like more information, please refer to the Committee's website, <http://www.house.gov/reform> under the header for transcripts. The transcript from the December 5, 2000, hearing is available under the title, "Accutane – Is this Acne Drug Treatment Linked to Depression and Suicide?" The FDA also maintains an information page on Accutane (<http://www.fda.gov/cder/drug/infopage/accutane/default.htm>) that includes the product labeling, informed consent form and Medication Guide.

If you have any questions or would prefer a printed copy of this transcript, please contact Professional Staff Member S. Elizabeth Clay at 202-225-5074 ([beth.clay@mail.house.gov](mailto:beth.clay@mail.house.gov)). Your assistance in this important matter is appreciated.

Sincerely,

/S/

Dan Burton  
Chairman